K081523

SEP 11 2008

## 2.0 510(k) Summary

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| Sponsor/Submitter: | Abbott Vascular<br>3200 Lakeside Drive<br>Santa Clara, CA 95054 |
| Contact Person: | Danielle Taylor<br>Regulatory Affairs Manager<br>Phone: (408) 845-0883<br>Fax:(408) 845-0921 |
| Date of Submission: | May 30, 2008 |
| Device Trade Name: | Emboshield NAV$^6$ Embolic Protection System |
| Device Common Name: | Embolic Protection System |
| Device Classification: | Class II |
| Regulation Number: | 21 CFR 870.1250 |
| Classification Name: | catheter, carotid, temporary, for embolization capture |
| Product Code: | NTE |
| Predicate Device: | Emboshield® Embolic Protection System (K052454) |
| Intended Use: | The Emboshield® Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm. |
| Device Description: | The Emboshield NAV$^6$ Embolic Protection System is a temporary percutaneous transluminal filtration system designed to capture embolic material released during angioplasty and stent procedures within carotid arteries. The system consists of the following components:<br><br>BareWire<br>The BareWire is a 0.014" PTFE coated stainless steel guidewire with a 3.0cm (0.014") platinum radiopaque distal tip section. Three BareWire designs are available as separately packaged items offering different support levels. |

The BareWire Workhorse is supplied with the Emboshield NAV$^6$ Embolic Protection System and is available packaged separately in two lengths, 315cm and 190cm.

RX Delivery Catheter
The RX Delivery Catheter usable length is 135 cm. The crossing profile is between 0.0365" and 0.0415", depending on Filtration Element size. A pull handle is used to deploy the loaded Filtration Element from the pod. Two pairs of indicator bands are provided along the catheter shaft. A proximal pair (90 cm and 100 cm from the catheter tip) to indicate the catheter tip position during advancement through the guide catheter, and a distal pair to indicate the proximity of the RX exit port during catheter retraction. A radiopaque marker band is positioned proximal to the pod.

Filtration Element
The Filtration Element consists of a nylon membrane with an internal nitinol support structure with radiopaque coils. There are two proximal triangular entry ports and multiple 120 micron distal perfusion pores. There is a proximal and a distal marker band. The Filtration Element is available in two sizes; small ($\phi$5.0mm) to treat vessel diameters of 2.5 – 4.8mm and large ($\phi$7.2mm) to treat vessel diameters of 4.0 to 7.0mm.

RX Retrieval Catheter
The RX Retrieval Catheter has a usable length of 139cm and a moulded, expansile distal tip with a maximum outer diameter of 0.067''. A handle is situated at the proximal end. Two pairs of marker bands indicate the position of the Retrieval Catheter RX guidewire exit port and catheter tip.

Summary of Substantial Equivalence:

Abbott Vascular has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the Emboshield NAV$^6$ Embolic Protection System is substantially equivalent to the currently marketed predicate device.

The Emboshield NAV$^6$ Embolic Protection System has the same intended use as the predicate device. Results of testing have demonstrated that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. *In vitro* and *in vivo* testing was conducted. The PROTECT Study was conducted enrolling a total of two hundred and twenty (220) patients at 34 sites.

In summary, the results of the testing and clinical study support the safety and performance of the Emboshield NAV$^6$ device and its components for the intended indication when used in accordance with the Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Abbott Vascular Inc.
c/o Ms. Danielle Taylor
Regulatory Affairs Manager
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K081523
RX Accunet® LP Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: August 15, 2008
Received: August 18, 2008

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K081523

**Device Name:** Emboshield NAV$^6$ Embolic Protection System

**Indications For Use:** The Emboshield NAV$^6$ Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in the carotid arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 mm and 7.0 mm.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchuen

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K081523